INFORMATION DISCLOSE

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 3

Substitute for Form 1449B/PTO

|                      | T TO/OB/OOM and OOD (modified) |  |
|----------------------|--------------------------------|--|
| Complete if Known    |                                |  |
| Application Number   | 10/595,999                     |  |
| Filing Date          | May 24, 2006                   |  |
| First Inventor       | Walzer et al.                  |  |
| Art Unit             | TBA                            |  |
| <b>Examiner Name</b> | TBA                            |  |
| Attorney Docket No.  | 91830.0542088                  |  |

|                       | U.S. PATENT DOCUMENTS    |  |                                    |                                  |  |       |
|-----------------------|--------------------------|--|------------------------------------|----------------------------------|--|-------|
| Examiner<br>Initials* | Cite<br>No.1             | <u>Document Number</u><br>Number - Kind Code <sup>2</sup><br>( <i>if known</i> )   | Publication Date<br>MM-DD-<br>YYYY | Name of Patentee or<br>Applicant | Pages, columns, lines when relevant passages or relevant figures appear        |       |
|                       |                          | US 2005/0113424  | 05-26-2005                         | Hayashi, et al.                  |  |       |
|                       |                          |  |                                    |                                  |  |       |
|                       | FOREIGN PATENT DOCUMENTS |  |                                    |                                  |  |       |
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| Examiner<br>Initials* | Cite<br>No.1             | Foreign Patent Document<br>Country Code <sup>3</sup> - Number <sup>4</sup> -<br>Kind Code <sup>5</sup> ( <i>if known</i> ) | Publication Date<br>MM-DD-<br>YYYY | Name of Patentee or<br>Applicant | Pages, columns, lines<br>where relevant passages or<br>relevant figures appear | $T^6$ |
|                       |                          | WO 2005/033065   | 04-14-2005                         | Tidwell et al.                   |  |       |
|                       |                          |  |                                    |                                  |  |       |
|                       |                          |  |                                    |                                  |  |       |

|                       | OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS |   |                |
|-----------------------|---|---|----------------|
| Examiner<br>Initials* | Cite<br>No.1                                    | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.                               | T <sup>6</sup> |
|                       |   | VANDEN EYNDE JEAN JACQUES ET AL: "Novel bisbenzamidines as potential drug candidates for the treatment of Pneumocystis carinii pneumonia." BIOORGANIC & MEDICINAL CHEMISTRY LETTERS. 6 SEP 2004, vol. 14, no. 17, 6 September 2004 (2004-09-06), pages 4545-4548, XP002374421 ISSN: 0960-894X |                |
|                       |   | TAO BIN ET AL: "Synthesis and anti-Pneumocystis carinii activity of conformationally restricted analogues of pentamidine" EUROPEAN JOURNAL OF MEDICINAL CHEMISTRY, vol. 34, no. 6, June 1999 (1999-06), pages 531-538, XP002374422 ISSN: 0223-5234  |                |
|                       |   | HUANG TIEN L ET AL: "N,N'-Bis(4-(N-alkylamidino)phenyl)homopiperazines as anti-Pneumocystis carinii agents" BIOORGANIC AND MEDICINAL CHEMISTRY LETTERS, vol. 11, no. 20, 22 October 2001 (2001-10-22), pages 2679-2681, XP002374423 ISSN: 0960-894X   |                |
|                       |   | HUANG TIEN L ET AL: "Synthesis and anti-Pneumocystis carinii activity of piperidine-linked aromatic diimidazolines" BIOORGANIC AND MEDICINAL CHEMISTRY LETTERS, vol. 6, no. 17, 1996, pages 2087-2090, XP002374424 ISSN: 0960-894X  |                |
|                       |   | BOYKIN D W ET AL: "Dicationic diarylfurans as anti-Pneumocystis carinii agents."  JOURNAL OF MEDICINAL CHEMISTRY. 17 MAR 1995, vol. 38, no. 6, 17 March 1995 (1995-03-17), pages 912-916, XP002374425 ISSN: 0022-2623.  |                |
|                       |   | BOYKIN D W ET AL: "2,5-bis[4-N-alkylamidino)phenyl]furans as anti-Pneumocystis carinii agents." JOURNAL OF MEDICINAL CHEMISTRY. 1 JAN 1998, vol. 41, no. 1, 1 January 1998 (1998-01-01), pages 124-129, XP002374426 ISSN: 0022-2623.  |                |
|                       |   | FRANCESCONI I ET AL: "2,4-Diphenyl furan diamidines as novel anti-Pneumocystis carinii pneumonia agents." JOURNAL OF MEDICINAL CHEMISTRY. 17 JUN 1999 (1999-06-17), pages 2260-2265, XP002374427 ISSN: 0022-2623.   |                |

| Examiner  | Date       |  |
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Sheet 2 of 3

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| Filing Date         | May 24, 2006                   |  |
| First Inventor      | Walzer et al.                  |  |
| Art Unit            | TBA                            |  |
| Examiner Name       | TBA                            |  |
| Attorney Docket No. | 91830.0542088                  |  |

| MAYENCE ANNIE ET AL: "Parallel solution-phase synethesis of conformationally   |  |
|--|--|
| restricted congeners of pentamidine and evaluation of their antiplasmodial activities."  |  |
| JOURNAL OF MEDICINAL CHEMISTRY. 6 MAY 2004, vol. 47, no. 10, 6 May   |  |
| 2004 (2004-05-06), pages 2700-2705, XP002374428 ISSN: 0022-2623.   |  |
| Beard, C. B., Carter, J. L., Keely, S. P., Huang, L., Pieniazek, N. J., Moura, I. N., Roberts, J. M., Hightower, A. W., Bens, M. S., Freeman, A. R., Lee, S., Stringer, J. R., |  |
| Duchin, J. S., del Rio, C., Rimland, D., Baughman, R. P., Levy, D. A., Dietz, V. J.,   |  |
| Simon, P., and Navin, T. R., Genetic variation in Pneumocystis carinii isolates from   |  |
| different geographic regions: implications for transmission.   |  |
| Emerg.Infect.Dis.2000.May-Jun.: 6, (3,): 265-72, 6, 265-272.   |  |
| Castro, M. (1998). Treatment and prophylaxis of Pneumocystis carinii pneumonia.  |  |
| Semin.Respir.Infect. 13. 296-303.  |  |
| Centers for Disease Control and Prevention (1999). Surveillance for AIDS-defining  |  |
| opportunistic illnesses 1993-1997. MMWR.Morb.Mortal.Wkly.Rep. 48 No. SS-2.   |  |
| Chen, F. and Cushion, M. T. (1994). Use of an ATP bioluminescent assay to evaluate   |  |
| viability of Pneumocystis carinii from rats. <i>J.Clin.Microbial.</i> 32, 2791-2800.   |  |
| Collins, M. S. and Cushion, M. T. (2001). Standardization of an in vitro drug screening  |  |
| assay by use of cryopreserved and characterized Pneumocystis carinii populations.  |  |
| J.Eukaryot.Microbiol. Supp: 178S-179S., 178S-179S.   |  |
| Cushion, M. T., Chen, F., and Kloepfer, N. (1997). A cytoxicity assay for evaluation of  |  |
| candidate anti-Pneumocystis carinii agents, Antimicrob Agents Chemother. 41, 379-384.  |  |
| Cushion, M. T., Collins, M., Hazra, B., and Kaneshiro, E. S. (2000). Effects of  |  |
| atovaquone and diospyrin-based drugs on the cellular ATP of <i>Pneumocystis carinii</i> f.   |  |
| sp. carinii.Antimicrob.Agents Chemother. 44, 713-719.  |  |
| Cushion, M. T., Ruffolo, J. J., Linke, M. J., and Walzer, P. D. (1985). <i>Pneumocystis</i>  |  |
| carinii: growth vegetables and estimates in the A549 and WI-38 VA13 human cell   |  |
| lines. Exp.Parasitol. 60, 43-54.   |  |
| Cushion, M. T., Stanforth, D., Linke, M. J., and Walzer, P. D. (1985). Method of testing   |  |
| the susceptibility of <i>Pneumocystis carinii</i> to antimicrobial agents in vitro.  |  |
| Antimicrob Agents Chemother. 28, 796-801.  |  |
| Cushion, M. T., and Walzer, P. D. (1984a). Cultivation of <i>Pneumocystis carinii</i> in lung-   |  |
| derived cell lines. J.Infect.Dis. 149, 644.  |  |
| Cushion, M. T., and Walzer, P. D. (1984b). Growth and serial passage of <i>Pneumocystis</i>  |  |
| carinii in the A549 cell line. Infect.Immun. 44, 245-251.  |  |
| Frenkel, J. K., Good, J. T., and Shultz, J. A. (1966). Latent Pneumocystis infection of rats, relapse, and chemotherapy. <i>Lab.Invest.</i> 15, 1559-1577.                     |  |
| Hughes, W. T., Gray, V. L., Gutteridge, W. E., Latter, V. S., and Pudney, M. (1990).   |  |
| Efficacy of a hydroxynaphthoquinone, 566C80, in experimental Pneumocystis carinii  |  |
| pneumonitis. Antimicrob. Agents Chemother. 34, 225-228.  |  |
| Kaneshiro, E. S., Collins, M., and Cushion, M. T. (1999). Effects of sterol inhibitors on  |  |
| the ATP content of Pneumocystis carinii, <i>J.Eukaryot.Microbiol.</i> 45, 142S-143S.   |  |
| Kazanjian, P., Armstrong, W., Hossler, P. A., Burman, W., Richardson, J., Lee, C. H.,  |  |
| Crane, L., Katz, J., and Meshnick, S. R., Pneumocystis carinii mutations are associated  |  |
| with duration of sulfa or sulfone prophylaxis exposure in AIDS patients.   |  |
| J.Infect.Dis. 2000.Aug.: 182. (2.):5517. 182, 551-557.   |  |
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| Kazanjian, P., Armstrong, W., Hossler, P. A., Lee, C. H., Huang, L., Beard, C. B.,   |  |
|--|--|
| Carter, J., Crane, L., Dutchin, J., Burman, W., Richardson, J., and Meshnick, S. R.,   |  |
| Pneumocystis carinii cytochrome b mutations are associated with atovaquone exposure  |  |
| in patients with AIDS. J.Infect.Dis.2001.Mar.1.:183(5.):81922. 183, 819-822.   |  |
| Ma, L., Borio, L., Masur, H., and Kovacs, J. A. (1999). Pneumocystis carinii   |  |
| dihydropteroate synthase but not dihydrofolate reductase gene mutations correlate with   |  |
| prior trimethoprimsulfamethoxazole or dapsone use. <i>J.Infect.Dis.</i> 180, 1969-1978.  |  |
| Mei, Q., Gurunathan, S., Masur, H., and Kovacs, J. A. (1998). Failure of cotrimoxazole in Pneumocystis carinii infection and mutations in dihydropteroate synthase |  |
| gene. Lancet 351, 1631-1632.   |  |
| Mills, J., Leoung, G., Medina, I., Hopewell, P. C., Hughes, W. T., and Wofsy, C. (1988)  |  |
| Dapsone treatment of Pneumocystis carinii pneumonia in the acquired  |  |
| immunodeficiency syndrome. Antimicrob. Agents Chemother. 32, 1057-1060.  |  |
| Walker, D. J., Wakefield, A. E., Dohn, M. N., Miller, R. F., Baughman, R. P., Hossler,   |  |
| P. A., Barlett, M. S. Smith, J. W., Kazanjian, P., and Meshnick, S. R. (1998). Sequence  |  |
| polymorphisms in the Pneumocystis carinii cytochrome b gene and their association  |  |
| with atovaquone prophylaxis failure. J.Infect.Dis. 178, 1767-1775.   |  |
| Walzer, P. D. (1991). Overview of animal models of Pneumocystis carinii pneumonia.<br>J.Protozool. 38, 122S-123S.  |  |
| Walzer, P. D., Ashbaugh, A., Collins, M., and Cushion, M. T. (2001), In vitro and in   |  |
| vivo effects of quinupristin-dalfopristin against Pneumocystis carinii.  |  |
| Antimicrob Agents Chemother. 45, 3234-3237.  |  |
| Walzer, P. D., Foy, J., Runck, J., Steele, P., White, M., Klein, R. S., Otter, B. A., and  |  |
| Sundberg, R. J. (1994). Guanylhydrazones in therapy of Pneumocystis carinii  |  |
| pneumonia in immunosuppresed rats. Antimicrob. Agents Chemother. 38, 2572-2576.  |  |
| Walzer, P. D., Foy, J., Steele, P., Kim, C. K., White, M., Klein, R. S., Otter, B. A., and   |  |
| Allegra, C. (1992a). Activities of antifolate, antiviral, and other drugs in an  |  |
| immunosuppressed rat model of Pneumocystis carinii pneumonia. <i>Antimicrob.Agents Chemother.</i> 36, 1935-1942.   |  |
| Walzer, P. D., Foy, J., Steele, P., and White, M. (1992b). Treatment of experimental   |  |
| pnumocystosis: review of 7 years of experience and development of a new system for   |  |
| classifying antimicrobial drugs. Antimicrob. Agents Chemother. 36, 1943-1950.  |  |
| Walzer, P. D., Runck, J., Orr, S., Foy, J., Steele, P., and White, M., (1997). Clinically  |  |
| used antimicrobial drugs against experimental pneumocystosis, singly and in  |  |
| combination: analysis of drug interactions and efficacies. Antimicrob.Agents   |  |
| Chemother. 41, 242-250.  |  |
| Wilkin, A. and Feinberg, J. (1999). Pneumocystis carinii pneumonia: a clinical review.   |  |
| Am.Fam.Physician. 60, 1699-4.  |  |

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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